

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic and/or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period.³ See Settlement Agreement §§ IV.B.1.a. & I.22.

2. (...continued)
not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. The Screening Period ended on January 3, 2003 for echocardiograms performed outside of the Trust's Screening Program and on July 3, 2003 for echocardiograms performed in the Trust's Screening Program. See Settlement Agreement § I.49.

In September, 2013, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Winston Gandy, Jr., M.D. Based on an echocardiogram dated February 18, 1998,⁴ Dr. Gandy attested in Part II of claimant's Green Form that Ms. Stissi suffered from mild aortic regurgitation, congenital aortic valve abnormalities, and aortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation.⁵ Dr. Gandy also attested that claimant had valvular repair or replacement surgery and required a second surgery through the sternum within eighteen months of the initial surgery due to prosthetic valve malfunction, poor fit, or complications reasonably related to the initial surgery.⁶ Based on such findings, claimant would be entitled to Matrix B-1, Level IV benefits in the amount of \$101,206.⁷

4. The attesting physician relied on the report of claimant's echocardiogram because claimant was unable to obtain a copy of the echocardiogram tape. See Settlement Agreement § VI.C.2.f. The Trust did not contest that claimant had submitted the affidavit required to rely on an echocardiogram no longer in existence.

5. Under the Settlement Agreement, the presence of congenital aortic valve abnormalities or aortic stenosis requires the payment of reduced Matrix Benefits for a claim based on damage to the aortic valve. See Settlement Agreement §§ IV.B.2.d.(2)(c)i)a) & IV.B.2.d.(2)(c)i)e).

6. Dr. Gandy also attested that claimant suffered from a reduced ejection fraction in the range of 50% to 60%. This condition is not at issue in this claim.

7. Under the Settlement Agreement, a claimant is entitled to
(continued...)

In the report of claimant's February 18, 1998 echocardiogram, the reviewing cardiologist, Anil V. Shah, M.D., F.A.C.C., stated, "By Doppler echocardiography, there is mild aortic insufficiency." Dr. Shah, however, did not specify a percentage as to claimant's level of aortic regurgitation. Under the definition set forth in the Settlement Agreement, mild or greater aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable) is equal to or greater than ten percent (10%) of the left ventricular outflow tract height ("LVOTH"). Settlement Agreement § I.22.

In November, 2013, the Trust forwarded the claim for review by Rohit J. Parmar, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Parmar determined there was no reasonable medical basis for Dr. Gandy's representation that Ms. Stissi had mild aortic regurgitation. Specifically, Dr. Parmar explained:

7. (...continued)

Level IV benefits if he or she "had valvular repair or replacement surgery and requires a second surgery through the sternum within eighteen months of the initial surgery due to prosthetic valve malfunction, poor fit, or complications reasonably related to the initial surgery." Settlement Agreement § IV.B.2.c.(4)(g). As the Trust does not contest that claimant has met these requirements, the only issue is whether she is eligible for benefits.

I reviewed the [echocardiogram] of 8-31-06; there is no [aortic regurgitation] on this [echocardiogram] of 8-31-06. I doubt there was AT LEAST MILD [aortic regurgitation] on 2-18-98. The report states "MILD [aortic regurgitation]"; if there was any [aortic regurgitation] it may have been TRACE.⁸

Based on Dr. Parmar's finding, the Trust issued a post-audit determination denying Ms. Stissi's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁹ In contest, Ms. Stissi argued that the auditing cardiologist's "goal was to erroneously fail this claim" and that he "selectively used data to fail this claim" by improperly relying on claimant's August 31, 2006 echocardiogram, while ignoring claimant's February 18, 1998 echocardiogram report. Claimant further asserted that while the Trust has a right pursuant to § VI.C.4.b. of the Settlement Agreement to consider other supporting documentation when the echocardiogram tape is no longer available, § VI.C.1.d. of the Settlement Agreement states that a

8. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, trace aortic regurgitation is defined as a JH/LVOTH ratio of less than 10%.

9. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Stissi's claim.

claimant cannot be disqualified from receiving Matrix Benefits if a subsequent echocardiogram does not reveal the required level of regurgitation. In addition, claimant contends that the auditing cardiologist violated the Audit Rules by not reviewing the declarations of the reviewing cardiologist, Dr. Shah, or the attesting physician, Dr. Gandy. Dr. Shah and Dr. Gandy submitted identical declarations, which stated, "In my opinion, based on a reasonable medical certainty, the February 18, 1998 echocardiogram exhibited mild aortic insufficiency."¹⁰

In further support of her claim, Ms. Stissi submitted a declaration of Ethan J. Podet, M.D., who stated, in pertinent part:

3. I find a reasonable medical basis for the Yes response given by Dr. Gandy, Question at Issue C.3.b., and finding of Mild Aortic Insufficiency regarding the 2/18/1998 study.

. . . .

8. I favor Dr. Gandy's and Dr. Shah's opinions over that of Dr. Parmar regarding the 2/18/1998 echocardiogram as Dr. Parmar's opinions are not based on the 2/18/1998 study.

9. I disagree with the statements of Dr. Parmar. Dr. Parmar did not review the images in question on the 2/18/1998 echocardiogram, only those obtained 8 years

10. Dr. Gandy's declaration erroneously states that the report for claimant's February 18, 1998 echocardiogram was his; the report actually was prepared by Dr. Shah.

later; valve had changed and is now stenotic as of 8/31/2006.

10. In my opinion, it is not reasonable for Dr. Parmar to challenge the specific findings of the 2/18/1998 report as he did not review the images in question.

Thus, according to claimant, she is entitled to Matrix Benefits because "[n]othing in this Audit challenges the reasonable medical basis for a finding of mild aortic insufficiency on the [February 18, 1998] report."

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist.

Dr. Parmar submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Stissi had mild aortic regurgitation. Dr. Parmar stated, in relevant part:

9. In accordance with the Trust's request, I reviewed the Claim and Claimant's Contest Materials. The February 18, 1998 echocardiogram of attestation is no longer in existence and was therefore not available for review. I considered the declaration of Dr. Podet, submitted at Contest, and re-reviewed the statements of Drs. Shah and Gandy, as well as the report of Claimant's February 18, 1998 echocardiogram. I also re-reviewed the available echocardiogram studies, dated August 9, 2002, August 31, 2006, and October 12, 2007.

10. Based on my review of the documentation submitted in support of this Claim, I again conclude that there is no reasonable medical basis to conclude that Claimant had mild aortic regurgitation at the time of the February 18, 1998 echocardiogram study.

There is no aortic regurgitation on the [echocardiogram] dated August 31, 2006. As I noted at audit, I think there was probably no aortic regurgitation, or only trace aortic regurgitation, at the time of the February 18, 1998 study. One would expect some [aortic regurgitation] on the [echocardiogram] of 2006 if there was [aortic regurgitation] in 1998.

11. I also reviewed the [echocardiogram] dated August 9, 2002, which was performed much closer in time to the 1998 study. The study is of poor quality. Color Doppler is seen in the parasternal long axis, short axis and apical views. Despite the very poor color imaging, I did not see any obvious diastolic turbulence at the level of the aortic valve. This would indicate that there was no significant aortic regurgitation on this [echocardiogram]. Moreover, the spectral Doppler shows no diastolic aortic regurgitation signal, again an indication of no significant aortic regurgitation.

12. Based on my review, I confirm my finding at audit that there is no reasonable medical basis for the Attesting Physician's representation that Claimant had mild aortic regurgitation. I also confirm my finding at audit, that there is no reasonable medical basis to conclude that Claimant had mild aortic regurgitation in between commencement of Diet Drug use and the close of the Screening Period.

The Trust then issued a final post-audit determination, again denying Ms. Stissi's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to

show cause why her claim should be paid. On August 11, 2014, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 9333 (Aug. 11, 2014).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on October 29, 2014, and claimant submitted a sur-reply on November 10, 2014. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹¹ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

11. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for finding that Ms. Stissi suffered from at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Stissi reasserts the arguments made in contest, namely, that Dr. Podet's declaration provides a reasonable medical basis for finding that claimant suffered from mild aortic regurgitation in 1998, prior to the end of the Screening Period and, therefore, claimant has established her eligibility for Matrix Benefits.¹² Claimant also contends

12. Claimant also refers to a medical record wherein one of her treating physicians, Allen Lew, M.D., noted that claimant had "mild aortic regurgitation." Dr. Lew, however, did not specify a percentage as to the level of claimant's aortic regurgitation. More significantly, in his report of claimant's August 9, 2002 echocardiogram, Dr. Lew made no finding of mild aortic regurgitation and found that claimant's aortic valve had "normal doppler."

that the auditing cardiologist "arbitrarily disregarded" the reviewing cardiologist's declaration and the report of claimant's February 18, 1998 echocardiogram.¹³ Finally, claimant asserts that the Settlement Agreement precludes the Trust from relying on claimant's August 31, 2006 echocardiogram to find that claimant is ineligible for Matrix Benefits.¹⁴

In response, the Trust argues that claimant did not establish a reasonable medical basis for Dr. Gandy's representation of mild aortic regurgitation. Specifically, the Trust contends that neither Dr. Podet's declaration nor the arguments advanced by claimant rebut Dr. Parmar's audit finding that Ms. Stissi had, at most, trace aortic regurgitation. Finally, the Trust asserts that the auditing cardiologist's finding is consistent with the Settlement Agreement, which

13. Claimant also asserts that the auditing cardiologist failed to address "Dr. Podet's medical opinion that worsening aortic stenosis is now affecting regurgitation levels of the later studies." Dr. Podet, however, never rendered such an opinion. In his declaration, Dr. Podet simply notes: "valve has changed and is now stenotic as of 8/31/2006."

14. To support this argument, claimant relies on this Court's decision in PTO No. 8897 (June 19, 2012). Claimant's reliance on PTO No. 8897, however, is misplaced. PTO No. 8897 did not address eligibility for Matrix Benefits. Rather, the issue in PTO No. 8897 was the applicability of the reduction factor of aortic sclerosis, the resolution of which depended on when the claimant was first diagnosed as FDA Positive. In that case, the later echocardiograms were properly used to support the findings of earlier echocardiograms no longer in existence that claimant was first diagnosed as FDA Positive before the age of 60. Accordingly, PTO No. 8897 does not support claimant's arguments that later echocardiograms can never be used by the Trust.

permits the Trust to rely on other echocardiographic studies in determining whether there is a reasonable medical basis for a claim.

In her sur-reply, claimant argues that the Trust ignored "the best" and "the most credible" evidence of the level of her aortic regurgitation, namely, the report of her February 18, 1998 echocardiogram, and instead improperly relied upon the speculative opinion of the auditing cardiologist.¹⁵

The Technical Advisor, Dr. Abramson, reviewed the claim and concluded that there was no reasonable medical basis for finding that Ms. Stissi had mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Specifically, Dr. Abramson explained, in pertinent part:

I reviewed the 2002 and 2006 echocardiograms on this Claimant. There was no aortic regurgitation on either study. The 2006 study demonstrated severe aortic stenosis. I also reviewed the intra-operative [transesophageal echocardiogram] performed on 10/25/2007, the day of her re-do aortic valve replacement. That study showed severe paravalvular regurgitation due to dehiscence of the aortic valve prosthesis with a large pseudoaneurysm.

The real issue in this case is if it is possible to have mild aortic regurgitation on

15. Claimant also asserts that her treating physicians did not rely on claimant's August 9, 2002 echocardiogram because they "recognized the lack of diagnostic capacity of the 2002 study." None of claimant's physicians, however, made any such assertion. Rather, Dr. Podet, Dr. Shah and Dr. Gandy made no mention at all of claimant's August 9, 2002 echocardiogram.

an echocardiogram in 1998, which completely disappears four years later. Aortic regurgitant lesions do not disappear. The normal progression is for them to stabilize or worsen. They can vary slightly from day to day based on hemodynamics such as blood pressure, blood volume, or medications, but they will not disappear completely.

Only Dr. Shah reviewed the original 1998 echocardiogram. Claimant's other physicians based their opinion of mild aortic regurgitation on Dr. Shah's report. None of them reviewed the actual study.

Based on the 2002 and 2006 echocardiograms, which demonstrated no aortic regurgitation, it is highly unlikely that there was any aortic regurgitation on the 1998 study. Accordingly, there is no reasonable medical basis for the Attesting Physician's claim that this claimant has mild aortic regurgitation.

After reviewing the entire Show Cause Record, claimant's arguments are without merit. As an initial matter, claimant does not refute the specific conclusions of the auditing cardiologist or the Technical Advisor¹⁶ that her August 9, 2002 and August 31, 2006 echocardiograms do not reveal the presence of at least mild aortic regurgitation.¹⁷ In particular, Dr. Parmar

16. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

17. As reflected in Dr. Parmar's declaration, contrary to claimant's argument, Dr. Parmar reviewed the entirety of claimant's medical records and support for the claim, including claimant's February 18, 1998 echocardiogram report as well as the declarations of Dr. Shah and Dr. Gandy. For this reason, we reject claimant's arguments that the auditing cardiologist "selectively used data to fail this claim," failed to "state the
(continued...)

noted that there was "no significant aortic regurgitation" on claimant's August 9, 2002 echocardiogram. Similarly, Dr. Abramson concluded that "[t]here was no aortic regurgitation" on Ms. Stissi's August 9, 2002 and August 31, 2006 echocardiograms. Claimant also did not address Dr. Abramson's finding that the absence of any aortic regurgitation on claimant's August 9, 2002 and August 31, 2006 echocardiograms makes it "highly unlikely" there was aortic regurgitation on claimant's February 18, 1998 echocardiogram because "[a]ortic regurgitant lesions do not disappear."¹⁸

Claimant counters that the Trust should not rely on her August 9, 2002 and August 31, 2006 echocardiograms in determining whether there was a reasonable medical basis for her attesting physician's representation of mild aortic regurgitation based on the report of her February 18, 1998 echocardiogram. In support of this argument, claimant relies on § VI.C.4.b. of the Settlement Agreement:

If the Class Member seeking a Matrix payment
is unable to obtain the [Medical Information]

17. (...continued)
underlying reasons for his opinions" and had the "goal" of seeking "to erroneously fail this claim."

18. The detailed review by both the auditing cardiologist and the Technical Advisor undermine claimant's assertions that she was denied a "fair review" of her claim and that the declaration and echocardiogram report of the reviewing cardiologist were "arbitrarily disregarded."

described above through the exercise of reasonable efforts, the Trustees and/or Claims Administrator(s) shall have the right to consider other supporting documentation including but not limited to declarations of other Qualified Physician(s) under penalty of perjury setting forth opinion(s) to a reasonable degree of medical certainty to support the claim that the Class Member's condition entitles him or her to a Matrix payment, subject to review by the Court as set forth in Section VIII.D. If this evidence establishes the Class Member's condition to the satisfaction of the Trustees and/or Claims Administrator(s), the Class Member shall be entitled to receive the appropriate Matrix Compensation Benefits.

Contrary to claimant's argument, nothing in this provision requires the Trust to consider only documents that support payment of a claim. Under the plain text of this provision, the Trust may "consider" other material and a claimant is only entitled to receive "appropriate" Matrix Benefits if the materials establish the necessary medical condition "to the satisfaction of the Trustees and/or Claims Administrator(s)."

Claimant is correct in noting that the Settlement Agreement, upon the satisfaction of certain conditions, allows a claimant to rely on the results of an echocardiogram when the echocardiogram itself can no longer be located. See Settlement Agreement §§ VI.C.2.e. & VI.C.2.f. However, nothing in the Settlement Agreement requires the Trust simply to accept the findings stated in an echocardiogram report where the echocardiogram tape is no longer in existence.

Further, claimant's argument ignores § VI.E.6. of the Settlement Agreement, which states:

In conducting an audit of those Claims and Requests for Credit selected for audit, the Trustees and/or Claims Administrator(s) shall follow the following procedure: All Accelerated Implementation Option acceptance form(s) ("PINK FORM"), registration form(s) ("BLUE FORM"), videotapes or disks of Echocardiograms, medical reports, and other information submitted by AHP in support of a Request for Credit or by a Class Member in support of a Claim, together with a copy of the claimant's medical records, and Echocardiogram videotapes or disks obtained by the Trustees/Claims Administrator(s) shall be forwarded to a highly-qualified, independent, Board-Certified Cardiologist (hereinafter referred to as the "Auditing Cardiologist") selected by the Trustees/Claims Administrator(s). After thoroughly reviewing these materials, the Auditing Cardiologist shall make a determination as to whether or not there was a reasonable medical basis for the representations made by any physician in support of the Claim or Request for Credit.

Id. § VI.E.6.; see also Audit Rule 7(a). Accepting claimant's interpretation would effectively negate this provision of the Settlement Agreement.¹⁹

Finally, claimant's interpretation is not supported by the parties responsible for drafting the Settlement Agreement, namely, Class Counsel and Wyeth. In October, 2010, we requested

19. For these reasons, we reject claimant's assertion that the report of her February 18, 1998 echocardiogram constitutes "the best" and "most credible" evidence of the level of aortic regurgitation necessary for Ms. Stissi to establish her eligibility for Matrix Benefits.

the views of Wyeth and Class Counsel as to the parties' intention with respect to §§ VI.C.4.b., VI.C.2.e., and VI.C.2.f. of the Settlement Agreement. See PTO No. 8549 (Oct. 18, 2010). In a joint response, Class Counsel and Wyeth stated their position as follows:

Where the tape or disk of the Qualifying Echocardiogram, the echocardiogram that supports the presence of a Matrix Level condition and/or the echocardiogram that supports the presence or absence of a Reduction Factor no longer exists or cannot be found, the Class Member must submit a sworn affidavit from the last custodian of the tape or disk documenting that such tape or disk no longer exists and explaining to the satisfaction of the Trust the circumstances under which the tape or disk "came to be misplaced or destroyed."

If the Class Member makes that showing, the Trust may rely upon other medical evidence regarding the presence or absence of the regurgitation diagnosed by the Qualifying Echocardiogram, the presence or absence of a Matrix Level condition, and the presence or absence of a Reduction Factor, including the written [echocardiogram] report of the missing tape or disk prepared when the echocardiogram was conducted and all other Medical Information submitted on the claim, such as hospital records, results of cardiac catheterizations, surgical reports, pathology reports, and any other echocardiogram studies. The Auditing Cardiologist shall weigh all such Medical Information and the totality of the medical facts presented in evaluating whether there is a reasonable medical basis for the level of regurgitation on the Qualifying Echocardiogram, the presence of a Matrix Level condition and the absence of pertinent reduction factors as asserted by the Attesting Physician in the

Green Form submitted by the Class Member in support of the Class Member's Matrix claim.

(Emphasis added.)

This is precisely what occurred here. While claimant was permitted to proceed with her claim upon submission of the required documentation to establish that her February 18, 1998 echocardiogram was no longer in existence, the Trust was permitted to consider, among other things, claimant's August 9, 2002 and August 31, 2006 echocardiograms in determining whether there was a reasonable medical basis for the attesting physician's representation. As a review of those materials revealed that the attesting physician's representation lacked a reasonable medical basis, the Trust properly denied claimant's request for Level IV Matrix Benefits.

Claimant's reliance on § VI.C.1.d. of the Settlement Agreement is similarly misplaced. This provision of the Settlement Agreement states:

A claimant who qualifies for a particular Matrix payment, by virtue of a properly interpreted Echocardiogram showing the required levels of regurgitation and/or complicating factors, after exposure to fenfluramine and/or dexfenfluramine, shall not be disqualified from receiving that Matrix payment in the event that a subsequent Echocardiogram shows that the required levels of regurgitation and/or complicating factors are no longer present.

Settlement Agreement § VI.C.1.d. Contrary to Ms. Stissi's argument, she had not yet "qualifie[d] for a particular Matrix

payment." In particular, we disagree with claimant that the report of her February 18, 1998 echocardiogram and the declarations of Dr. Podet, Dr. Shah, and Dr. Gandy established a reasonable medical basis for her claim that she was qualified to receive Level IV Matrix Benefits under the Settlement Agreement. As such, the Trust did not, as claimant contends, violate § VI.C.1.d. of the Settlement Agreement by considering claimant's August 9, 2002 and August 31, 2006 echocardiograms.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Therefore, we will affirm the Trust's denial of Ms. Stissi's claim for Matrix B-1, Level IV benefits.